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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/510,687 | 05/19/2005 | Gilbert Pallas | 0581-1008 | 4019 |

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ARLINGTON, VA 22202

EXAMINER

HILL, LAURA C

| ART UNIT | PAPER NUMBER |
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3761

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.



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| APPLICATION NO/ CONTROL NO. | FILING DATE | FIRST NAMED INVENTOR / PATENT IN REEXAMINATION | ATTORNEY DOCKET NO. |
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10/510,687

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| ART UNIT | PAPER |
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20051024

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/510,687 | Applicant(s) PALLAS, GILBERT | |
| | Examiner Laura C. Hill | Art Unit 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>10/8/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

1. Claim 11 is objected to because of the following informalities: there is no claim dependency. Appropriate correction is required.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the 'wall vacuum source' as recited in claim 1 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Language Interpretation

3. For examination purposes 35 U.S.C. 112, sixth paragraph or the "means or step plus function" limitation has been invoked with regards to claims 1 and 10-12. It is noted that the 'means for loosening solid fecal matter' and 'means for sucking up the cleansing liquid and the loose fecal matter' comprise an operating handle with switch and a tube connected to a wall vacuum source, respectively as defined on page 4 of the specification.

4. For examination purposes, claim 11 is interpreted to be dependent from claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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5. Claims 1-2 and 5-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al. (WO 99/43365A1; herein 'Hill') in view of Holt (US 4,190,059; herein 'Holt'). Regarding claims 1 and 10 Hill discloses a colonic lavage device 11 which acts to loosen and dislodge impacted fecal material in a patient's colon (page 11, lines 5-7), the device 11 comprising a cylindrical main body 12 with valve assembly allowing fluid to flow through at its distal end (page 15, lines 22-26, page 18, lines 24-page 19, line 1, figure 2) and having a shoulder/strainer 15 at end portion 14 (page 16, lines 25-page 17, line 2), pulsed flow means for dislodging and loosening fecal material (page 22, lines 10-13), pressurized air hose connected to pressure chamber 21/means for sucking up the cleansing liquid (page 18, lines 18-23, figure 2), the device 11 comprises:

Two flexible coaxial tubes 17, 18 having the length of the colon and separated by pressure chamber/gap 21 (page 16, lines 21-24), the outer shell/tube 17 formed of flexible silicone rubber compound and thus being adaptable to the colon's shape (page 16, lines 1-13), the interior tube 18 drains cleansing liquid and fecal matter, and pressure chamber/gap 21 provides a passage for cleansing liquid (page 17, lines 2-7, page 19, lines 18-page 20, line 5); and

A toroidal silicone rubber speculum/introducer 78, 171 configured and sized to be inserted into a patient's rectum through which lavage liquid passes into a patient's colon and through which waste liquid passes from the colon and through the speculum for disposal and through which two coaxial tubes 172, 178 slide (page 24, lines 21-27, page 39, lines 19-23, figure 10).

Hill *does not expressly disclose* the means for loosening solid fecal matter includes a handle with a switch. **Holt** discloses a colonic lavage apparatus 10 with fecal pressure limiting valve/suction means 40 and loosening means via an irrigation process with drain shutoff valve 94 provided with lever/handle 112 and on-off switch 108 (col. 4, ll. 28-31, col. 5, ll. 10-18, col. 6, ll. 52-60, col. 7, ll. 30-47). One would be motivated to modify the loosening means of Hill with the handle and switch of Holt to provide an operator-controlled loosening means mechanism since both references are in the same field of endeavor; colonic lavage devices with loosening and suction means. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the loosening means, thus providing a handle and switch loosening means.

Regarding claims 2 and 9 Hill further discloses a shoulder/strainer 15 with female coupling nipple/mechanical sweeping and brushing device 16 (page 17, lines 1-2, figures 1-2).

Regarding claims 5-7 Hill further discloses the strainer 15 is terminated by end cap 13 (page 15, lines 25-26, figure 1). Hill *does not expressly disclose* the length, hole distances and diameters, tube diameters or cleansing liquid rate values. Length, hole distances and diameters, tube diameters and cleansing liquid rate values are result-effective variables since they are at least dependent on the overall apparatus size. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify Hill with length, hole distances and diameters, tube diameters, and cleansing liquid rate values, since it has been held that discovering an optimum value of

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a result effective variable involves only routine skill in the art. *In re Boesch and Slaney*, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claim 8 Hill further discloses the interior tube 18, outer tube 17, and main body 12 (main body 12 includes shoulder 15) are formed of a flexible silicone or silicone rubber compound (page 15, line 27-page 16, line 13).

Regarding claim 11 Holt discloses pressure limiting valve/suction means 40 (column 5, lines 14-16), water mixing valve/irrigation means 24 (column 4, lines 55-64) and speculum/loosening means 70 (column 6, lines 52-65) are operated via independent voluntary controls (figure 1).

Regarding claim 12 Hill/Holt disclose the handle with switch loosening means as discussed above with respect to claim 1. Hill further discloses pressurized air can originate from any appropriate source connected to the other end of the supply line 39, such as, for example, a pump or pressurized air tank and associated control system, a hand operated pump, or other source (page 20, lines 24-27). Hill *does not expressly disclose* the irrigation means comprise a foot-operated control pedal. One would be motivated to modify the hand-operated pump to include a control pedal operated by any other part of the body since Hill discloses the irrigation pump can be operated by any source. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the hand-controlled pump, thus providing a foot-operated pump.

Regarding claim 13 Hill *does not expressly disclose* a pressurized safety appliance. **Holt** discloses an oxygen pressure regulator and shutoff valve/pressurized

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safety appliance 116 (column 7, lines 54-column 8, line 7). One would be motivated to modify the colonic lavage device of Hill with the safety appliance of Holt to provide a back-up safety mechanism since both references disclose colonic lavage devices with loosening and suction means. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the device, thus providing a pressurized safety appliance.

6. Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al. (WO 99/43365A1; herein 'Hill') in view of Holt (US 4,190,059; herein 'Holt') as applied to claim 1 above, and further in view of Derouineau (US 3,888,427; herein 'Derouineau'). Hill/Holt *do not expressly disclose* the inner tube includes a rotating device such as a rotary knife for grinding fecal matter. **Derouineau** discloses disposal unit 1 with suction pump 2 and grinding member for matter discharged from water closets (column 1, lines 3-5), the grinding member comprises a rotating vertical grinding teeth 19 shaft 11 pressed against a grid 10 (column 3, lines 4-24) that finely grinds fecal matter and other soft materials (column 2, lines 10-13). One would be motivated to modify the colonic lavage device of Hill with the rotary grinder of Derouineau to facilitate fecal matter grinding since both references disclose bodily waste disposal units with suction means. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the colonic lavage, thus providing a rotating grinding device.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Hill whose telephone number is 571-272-7137. The examiner can normally be reached on Monday through Friday (off every other Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura C. Hill
Examiner
Art Unit 3761

LCH



TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

